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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,990	03/18/2004	Niall Duffy	PA1947 US	8931

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MEDTRONIC VASCULAR, INC.
IP LEGAL DEPARTMENT
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EXAMINER

PICKETT, JOHN G

ART UNIT	PAPER NUMBER
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3728

DATE MAILED: 09/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/804,990

Applicant(s)

DUFFY ET AL.

Examiner

Gregory Pickett

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 9-11 and 16-18 is/are rejected.
- 7) ☒ Claim(s) 4-8, 12-15 and 19-22 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 March 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Priority

1. This application repeats a substantial portion of prior Application No. 10/251,575, filed 20 September 2002, and adds and claims additional disclosure not presented in the prior application. Since this application names an inventor or inventors named in the prior application, it may constitute a continuation-in-part of the prior application. Should applicant desire to obtain the benefit of the filing date of the prior application, attention is directed to 35 U.S.C. 120 and 37 CFR 1.78.

Drawings

2. Figures 1-5 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). Corrected drawings in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the examiner does not accept the changes, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1 and 2 are rejected under 35 U.S.C. 102(e) as being anticipated by Kavanagh et al (US 6,578,709; hereinafter Kavanagh).

Claim 1: Kavanagh discloses a catheter-packing device **24** with a tubular body **25** having a passageway **33**, proximal section **26** with an oval cross-section (see Figure 5), distal section **27**, and resilient member **50**.

Claim 2: distal section has a circular cross-section at portion **40**.

4. Claims 1, 2, 9, 10, 16, and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by Duffy et al (US 2004/0055926 A1; hereinafter Duffy).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claim 1: Duffy discloses a packing device **40** with a tubular body **82** having a passageway **88**, a proximal end **84** having a substantially oval cross-section (see Figure 3), a distal end **86**, and resilient members **96 & 98**.

Claim 2: Duffy discloses distal end **86** with a circular cross-section.

Claims 9 and 10: Duffy discloses a packing device **40** with a tubular body **82** having a passageway **88**, a proximal end **84** having a substantially oval cross-section (see Figure 3), a distal end **86**, resilient members **96 & 98**, and flexible tube **20** capable of being coiled as claimed (see Figure 3).

Claim 16: Duffy discloses an elongated flexible catheter **16** with a proximal shaft **52**, distal shaft **50**, first lumen **58**, second lumen **56**, longitudinal guide way **74**, stop member **100**, guide member **32**, packing hoop **20**, packing component **40** with a tubular body **82** having a passageway **88**, a proximal end **84** of a substantially oval cross-section (see Figure 3), a distal end **86** of a substantially circular cross-section (see Figure 3), and resilient members **96 & 98**.

Claim 17: Duffy discloses fitting **36** and oval section **84** arranged as claimed (see Figure 4).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 3, 11, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duffy as applied to claims 2, 10, and 17 above, and further in view of Peckels et al (US 5,186,326; hereinafter Peckels).

Duffy discloses the claimed invention except that Duffy uses deformable, shaped resilient walls instead of a resilient member formed from first and second slots. Peckels shows that a resilient member **36**, formed from first and second slots (straight portions of cut-out **38**), was an equivalent structure known in the art for resiliently retaining an inserted object. Therefore, because these two retention means were art-recognized equivalents at the time the invention was made, one of ordinary skill in the art would have found it obvious to substitute the resilient member formed from first and second slots of Peckels, for the deformable, shaped resilient walls of Duffy.

6. Claims 1-3 and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Farrell et al (US 6,053,313; hereinafter Farrell) in view of Peckels.

Claims 1-3: Farrell discloses a catheter-packing device **5** with a tubular body **50** having a passageway (see Figures 5 & 6), proximal section **504**, and distal section **501**.

Farrell lacks, or does not expressly disclose an oval cross-section, nor a resilient member projecting into the passageway.

As to the oval cross-section, the examiner takes Official Notice that it was known

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in the art at the time the invention was made to closely conform the shape of a packaging sleeve to the shape of the retained article. Such conforming shape is well known to reduce the movement of the retained articles during transport. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the device of Farrell with an oval cross-section in order to closely retain an oval-shaped, catheter fitting. A change in form or shape is generally recognized as being within the level of ordinary skill in the art, absent any showing of unexpected results. *In re Dailey et al.*, 149 USPQ 47. Since the catheter itself was well known to be circular, the retention of the circular cross-section at the distal portion of the device would have been obvious.

As to the resilient member, Peckels discloses a resilient member **36** formed from first and second slots (straight portions of cut-out **38**) used in a packaging device designed to frictionally retain an article such that the article doesn't slip from the retaining device. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the device of Farrell with a resilient member as taught by Peckels in order to frictionally retain the held article.

Claims 9-11: Farrell-Peckels, as applied to claims 1-3, discloses the claimed invention, including the flexible tube (Farrell, **3**).

7. Claims 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Euteneuer et al (US 5,171,222; hereinafter Euteneuer) in view of Farrell and Peckels.

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Euteneuer discloses a catheter with an elongated, flexible shaft **12** having portions at a proximal end **24** and a distal end **18**, first lumen **16**, and second lumen **14**; a longitudinal guide way **30**; a stop **52**; and a guide member **46**. Euteneuer is inherently capable of functioning as claimed and merely lacks the packaging hoop with packaging component, and the oval shape.

Farrell discloses a packaging hoop **3** and a packing component **5** with a tubular body **50** having a passageway (see Figures 5 & 6), proximal section **504**, and a substantially circular distal section **501**. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the catheter of Euteneuer in a packaging as taught by Farrell in order to protect the catheter during transport.

As to the oval cross-section, the examiner takes Official Notice that it was known in the art at the time the invention was made to closely conform the shape of a packaging sleeve to the shape of the retained article. Such conforming shape is well known to reduce the movement of the retained articles during transport. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide device **5** of Farrell with an oval cross-section in order to closely retain the guide member **46** of Euteneuer. A change in form or shape is generally recognized as being within the level of ordinary skill in the art, absent any showing of unexpected results. *In re Dailey et al.*, 149 USPQ 47. Since the catheter itself was well known to be circular, the retention of the circular cross-section at the distal portion of device **5** would have been obvious.

As to the resilient member, Peckels discloses a resilient member 36 formed from first and second slots (straight portions of cut-out 38) used in a packaging device designed to frictionally retain an article such that the article doesn't slip from the retaining device. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the assembly of Euteneuer-Farrell with a resilient member as taught by Peckels in order to frictionally retain the guide member.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1-3, 9-11, and 16-18 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 5 of copending Application No. 10/251,575 in view of Peckels.

Claims 16 and 17: Claim 5 discloses the claimed invention except for the oval shape. The examiner takes Official Notice that it was known in the art at the time the invention was made to closely conform the shape of a packaging sleeve to the shape of

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the retained article. Such conforming shape is well known to reduce the movement of the retained articles during transport. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the component of claim 5 with an oval cross-section in order to closely retain the guide member. A change in form or shape is generally recognized as being within the level of ordinary skill in the art, absent any showing of unexpected results. *In re Dailey et al.*, 149 USPQ 47. Since the catheter itself was well known to be circular, the retention of the circular cross-section at the distal portion of the component of claim 5 would have been obvious.

Claim 18: Claim 5 discloses the claimed invention except that Claim 5 uses a resilient arm instead of a resilient member formed from first and second slots. Peckels shows that a resilient member **36**, formed from first and second slots (straight portions of cut-out **38**), was an equivalent structure known in the art for resiliently retaining an inserted object. Therefore, because these two retention means were art-recognized equivalents at the time the invention was made, one of ordinary skill in the art would have found it obvious to substitute the resilient member formed from first and second slots of Peckels, for the resilient arm of claim 5.

Claims 1-3 and 9-11: the combination of Claim 5 and Peckels discloses the claimed invention except that claim 9 omits the catheter itself and claim 1 omits the coiled tubing. It would have been obvious to one having ordinary skill in the art at the time the invention was made to omit the claimed elements, since it has been held that omission of an element and its function in a combination where the remaining elements

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perform the same function as before involves only routine skill in the art. *In re Karlson*, 136 USPQ 184.

This is a provisional obviousness-type double patenting rejection.

Allowable Subject Matter

9. Claims 4-8, 12-15, and 19-22 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory Pickett whose telephone number is 571-272-4560. The examiner can normally be reached on Mon-Fri, 11:30 AM - 8:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu can be reached on 571-272-4562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Greg Pickett
Examiner
16 September 2005



Mickey Yu
Supervisory Patent Examiner
Group 3700